Hemogram

Western Pennsylvania Chapter of the National Hemophilia Foundation

January 2013

Inside this issue

DESIGNATE UNITED WAY GIFTS TO THE CHAPTER!

If your company is participating in the United Way campaign, you may designate all or a portion of your gift to the Chapter.

WPCNHF Contributor Agency Code Number is: **83**

OKTOBERFEST

Port Farms in Waterford, PA, was the location of the 2012 Oktoberfest, held on October 13. Scott E. Miller, CPA, Esq., DBA, WPCNHF's Board President presented the program Planning Your Future. This program was packed with useful financial planning information for people of all ages. In fact, the earlier one starts saving, the better. Scott recommends that when you receive your pay, you should pay yourself first, by putting 10% of your money into savings. He encourages kids to start this savings habit from the time they begin to receive an allowance. Scott also talked about the importance of having a good credit report. Did you know that it's common for employers to check credit reports during the hiring process? If you choose to voluntarily close an account, be sure to request that the credit card company notes the account was closed at the customer's request; otherwise, the account closure could be interpreted negatively. Scott had lots of great advice to offer throughout the session. If you missed this wonderful program, be sure to attend the next time it is offered! You'll be glad you did.

Following the program, attendees were free to enjoy the many activities that Port Farms had to offer. The fun included hayrides, a corn maze, giant slides, a pedal cart raceway, and more!

Take-A-Bough

The 3rd Annual Take-A-Bough was held at the Shops at Station Square, November 16-19. It was an exciting year for the Chapter, as we raised over $57,000! We are extremely grateful for the donations we received from our Chapter members, our partner organizations and the new donors who offered their support for the first time.

Planning and preparation for the 3rd Take-A-Bough began back in February! We couldn't have done it without the hard work and dedication of our volunteer planning committee. Special thanks to the following committee members: Anne Graham, Dawn Rotellini, Debbie Lowery, Denise Murray, Diane Standish, James Constantin, Laureen Temple, Maria Steele Voms Stein, Melissa Kendrick, Nora Latcovich, and Rita Dull. Once again, Casey Mahaven of Mahaven Events was on hand to help as well.

During the week of November 12-15, numerous volunteers helped transform a former nightclub into a holiday

Continued on page 13

LETTER FROM THE PRESIDENT, SCOTT MILLER

Members and Stakeholders of the WPCNHF,

Welcome to 2013 and to a re-invigorated Western Pennsylvania Chapter of the National Hemophilia Foundation. We are coming off of one of our most successful years in memory and look forward to continuing our growth and development as a Chapter. With the continued success of the Walk and increasing popularity of Take-A-Bough, I am confident that the Chapter will be able to continue toward its strategic goals and objectives in swift fashion. This past year has been one of change for the Chapter – we saw a change in leadership in the Executive Director, change in membership on the Board, a new, revitalized website, changes in the organizational structure, and changes in our fundraising – all of which have resulted in our ability to better serve the bleeding disorders community.

I am so proud of the leadership that our new Executive Director, Alison Yazer, has shown in her first four months. She has brought fresh ideas and great leadership experience to continue the progress that Jennifer Wahlen-Pegher had begun. Over the next few months, Alison will be utilizing the data we received from the Chapter Needs Assessment to help the Board update its strategic plan. Given the success of our fundraising and grantsmanship this past year, you will see more diversity and geographic outreach in our programming so that more of you can be part of the wonderful programs and events we have to offer.

I want to thank Madonna McGuire Smith for her years of service to the Chapter. Madonna started as our Walk Manager, growing that into one of our premiere fundraising and awareness programs. She also added Run for Their Lives® which added depth and liveliness to the Walk event. Perhaps most importantly, Madonna brought us Take-A-Bough® which has grown into the most successful fundraiser AND, just as importantly, one of our most successful awareness campaigns in our history. This will leave a legacy for our future success as we embark on increasing our focus on education, advocacy, resource and referral. These four elements of our mission are critical to our membership and we, as a board, are committed to the chapters continued growth and vitality in these areas.

I want to thank you all for your continued support over the transition this past year and I wish you all a safe and happy new year. Please remember to watch our event calendar in the newsletter and on our website for future events.

Sincerely,
Scott E. Miller, CPA, J.D., DBA
WPCNHF Board President

LETTER FROM THE EXECUTIVE DIRECTOR

Dear Chapter Members and Friends,

After four months under my belt as the new Executive Director of WPCNHF, I am finally finding my sea legs. It has been a very busy adjustment period, with Oktoberfest, the NHF Annual Meeting, Take-A-Bough and Winterfest! I really enjoyed each of these programs, especially since they afforded me an opportunity to meet so many of you!

I am looking forward to an exciting 2013 – with lots of exciting programs and events. Check out the calendar for the dates of some of them. We are always interested in hearing what sort of educational events and programs you're looking for, so please don't hesitate to call the office or email us with your suggestions.

One of the hardest things I've had to do in my new role was to accept the resignation of Madonna McGuire Smith. After nearly 4 years of service, we have to say goodbye to Madonna. She and her family will be relocating to Oregon, where her husband, Mike, has secured a new job. Madonna not only brought the annual Walk and Take-A-Bough to us, she also brought her passion and energy to the chapter. We will miss her terribly and wish both she and her family the best of luck as they embark on the next chapter of their lives!

Alison Yazer
Executive Director

Madonna McGuire Smith and her family.

Calendar of Upcoming Events

Thursday, February 7
Advocacy 101 Program and Dinner
Robinson Township, PA

Wednesday, February 27 – Friday, March 1
Washington Days
Washington, D. C.

Saturday, March 2
Infusion Day
Cranberry Township, PA

Sunday, July 28
WPCNHF Annual Meeting and Walk Kickoff
North Park, Allison Park, PA

Sunday, August 4 – Saturday, August 10
Camp Hot-to-Clot
Fombell, PA

Saturday, September 21
Hemophilia Walk
North Park, Allison Park, PA

Saturday, September 21
Run For Their Lives
North Park, Allison Park, PA

Thursday, October 3 – Saturday, October 5
NHF Annual Meeting
Anaheim, CA

Saturday, October 26
Educational Program and Social Event
Erie, PA

Friday, November 22 – Sunday, November 24
Take-A-Bough
Pittsburgh, PA

CFC® Combined Federal Campaign

Combined Federal Campaign

WPCNHF is an approved charitable organization for the Combined Federal Campaign (CFC). If you participate in the CFC, please consider designating all or a portion of your donation to the Chapter.

WPCNHF CFC Number is: 81343

CASH FOR TRASH FUNDRAISER

Recycle your inkjet and toner cartridges

Cartridges can be brought from home, work, or local businesses. Be sure to ask your employer to sponsor us by saving their empty toner cartridges. We receive funds for the Chapter for empty laser, fax, and copier cartridges. Inkjet cartridges can earn money too! Recycling cartridges not only helps to alleviate America's landfills, it makes "cents" too! All money earned from this program will go to WPCNHF. Please drop empty cartridges at:

WPCNHF
20411 Route 19, Unit 14
Cranberry Twp., PA 16066

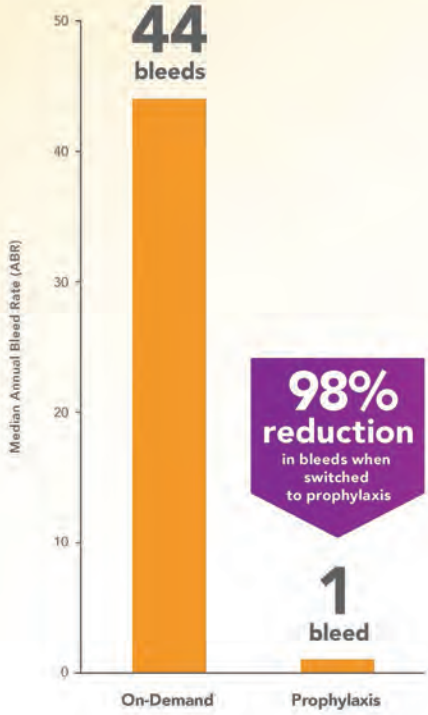
Ask us about sponsorship opportunites and how you can help!

Prophylaxis with ADVATE delivers 44 to 1[1]

ADVATE IS THE **ONLY** RECOMBINANT FACTOR VIII (EIGHT) THAT IS FDA APPROVED FOR PROPHYLAXIS IN BOTH **ADULTS & CHILDREN (0-16 YEARS)**[1-3]

PROPHYLAXIS WITH ADVATE

THE POWER TO REDUCE YOUR ANNUAL BLEED RATE (ABR)



ADVATE
[Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method]
There's more to life.

advate.com | 888.4.ADVATE

Significant reduction in ABR[1]

After switching from 6 months of on-demand treatment to 12 months of prophylaxis with ADVATE in 53 previously treated patients with severe or moderately severe hemophilia A:

- **Median ABR of 1** while on either prophylaxis regimen[1]
  - prophylaxis every second day (20-40 IU/kg)
  - prophylaxis every third day (20-80 IU/kg, targeted to maintain FVIII trough levels ≥1%)
- **42% of patients experienced zero bleeds** during 1 year on prophylaxis[1]
- **No subject developed factor VIII inhibitors** or withdrew due to an adverse event (AE)[4]

Indication for ADVATE

ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] is a medicine used to replace clotting factor VIII that is missing in people with hemophilia A (also called "classic" hemophilia). ADVATE is used to prevent and control bleeding in people with hemophilia A. Your healthcare provider may give you ADVATE when you have surgery.

ADVATE is not used to treat von Willebrand Disease.

Detailed Important Risk Information for ADVATE

You should not use ADVATE if you are allergic to mice or hamsters or any ingredients in ADVATE.

You should tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines and dietary supplements, have any allergies, including allergies to mice or hamsters, are nursing, are pregnant, or have been told that you have inhibitors to factor VIII.

You can have an allergic reaction to ADVATE. Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea, or fainting.

Your body may form inhibitors to factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop ADVATE from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

Side effects that have been reported with ADVATE include: cough, sore throat, unusual taste, abdominal pain, diarrhea, nausea/vomiting, headache, fever, dizziness, hot flashes, chills, sweating, joint swelling/aching, itching, hematoma, swelling of legs, runny nose/congestion, and rash.

Call your healthcare provider right away about any side effects that bother you or if your bleeding does not stop after taking ADVATE.

Please see Brief Summary of ADVATE Prescribing Information on the adjacent page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

References: 1. ADVATE prescribing information. Westlake Village, CA: Baxter Healthcare Corporation; December 2011. **2.** Helixate FS prescribing information. Kankakee, IL: CSL Behring LLC; August 2009. **3.** Kogenate FS prescribing information. Tarrytown, NY: Bayer Healthcare LLC; March 2011. **4.** Valentino LA, Mamonov V, Hellmann A, et al. A randomized comparison of two prophylaxis regimens and a paired comparison of on-demand and prophylaxis treatments in hemophilia A management. *J Thromb Haemost.* 2012;10(3):359-367.

TALK TO YOUR HEALTHCARE PROVIDER TO SEE IF PROPHYLAXIS WITH ADVATE CAN HELP REDUCE YOUR ANNUAL BLEED RATE (ABR)

ADVATE
[Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method]
Brief Summary of Prescribing Information. Please see package insert for full prescribing information.

INDICATIONS AND USAGE

Control and Prevention of Bleeding Episodes

ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] is an Antihemophilic Factor (Recombinant) indicated for control and prevention of bleeding episodes in adults and children (0-16 years) with Hemophilia A.

Perioperative Management

ADVATE is indicated in the perioperative management in adults and children (0-16 years) with Hemophilia A.

Routine Prophylaxis

ADVATE is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children (0-16 years) with Hemophilia A.

ADVATE is not indicated for the treatment of von Willebrand disease.

CONTRAINDICATIONS

Known anaphylaxis to mouse or hamster protein or other constituents of the product.

WARNINGS AND PRECAUTIONS

Anaphylaxis and Hypersensitivity Reactions

Allergic-type hypersensitivity reactions, including anaphylaxis, are possible and have been reported with ADVATE. Symptoms have manifested as dizziness, paresthesias, rash, flushing, face swelling, urticaria, dyspnea, and pruritus. [See Patient Counseling Information (17) in full prescribing informaiton]

ADVATE contains trace amounts of mouse immunoglobulin G (MuIgG): maximum of 0.1 ng/IU ADVATE and hamster proteins: maximum of 1.5 ng/IU ADVATE. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

Discontinue ADVATE if hypersensitivity symptoms occur and administer appropriate emergency treatment.

Neutralizing Antibodies

Carefully monitor patients treated with AHF products for the development of Factor VIII inhibitors by appropriate clinical observations and laboratory tests. Inhibitors have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures Factor VIII inhibitor concentration. [See Warnings and Precautions, Monitoring Laboratory Tests]

Monitoring Laboratory Tests

The clinical response to ADVATE may vary. If bleeding is not controlled with the recommended dose, determine the plasma level of Factor VIII and administer a sufficient dose of ADVATE to achieve a satisfactory clinical response. If the patient's plasma Factor VIII level fails to increase as expected or if bleeding is not controlled after the expected dose, suspect the presence of an inhibitor (neutralizing antibodies) and perform appropriate tests as follows:

- Monitor plasma Factor VIII activity levels by the one-stage clotting assay to confirm the adequate Factor VIII levels have been achieved and maintained when clinically indicated. [See Dosage and Administration (2) in full prescribing information]
- Perform the Bethesda assay to determine if Factor VIII inhibitor is present. If expected Factor VIII activity plasma levels are not attained, or if bleeding is not controlled with the expected dose of ADVATE, use Bethesda Units (BU) to titer inhibitors.
  - If the inhibitor titer is less than 10 BU per mL, the administration of additional Antihemophilic Factor concentrate may neutralize the inhibitor and may permit an appropriate hemostatic response.
  - If the inhibitor titer is above 10 BU per mL, adequate hemostasis may not be achieved. The inhibitor titer may rise following ADVATE infusion as a result of an anamnestic response to Factor VIII. The treatment or prevention of bleeding in such patients requires the use of alternative therapeutic approaches and agents.

ADVERSE REACTIONS

The serious adverse drug reactions (ADRs) seen with ADVATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to Factor VIII.

The most common ADRs observed in clinical trials (frequency ≥ 10% of subjects) were pyrexia, headache, cough, nasopharyngitis, vomiting, arthralgia, and limb injury.

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in clinical practice.

ADVATE has been evaluated in five completed studies in previously treated patients (PTPs) and one ongoing study in previously untreated patients (PUPs) with severe to moderately severe Hemophilia A (Factor VIII ≤ 2% of normal). A total of 234 subjects have been treated with ADVATE as of March 2006. Total exposure to ADVATE was 44,926 infusions. The median duration of participation per subject was 370.5 (range: 1 to 1,256) days and the median number of exposure days to ADVATE per subject was 128.0 (range: 1 to 598).[1]

The summary of adverse reactions (ADRs) with a frequency ≥ 5% (defined as adverse events occurring within 24 hours of infusion or any event causally related occurring within study period) is shown in Table 1.

No subject was withdrawn from a study due to an ADR. There were no deaths in any of the clinical studies.

IMMUNOGENICITY

The development of Factor VIII inhibitors with the use of ADVATE was evaluated in clinical studies with pediatric PTPs (< 6 years of age with > 50 Factor VIII exposures) and PTPs (≥ 10 years of age with > 150 Factor VIII exposures). Of 198 subjects who were treated for at least 10 exposure days or on study for a minimum of 120 days, 1 adult developed a low-titer inhibitor (2.0 [BU] in the Bethesda assay) after 26 exposure days. Eight weeks later, the inhibitor was no longer detectable, and *in vivo* recovery was normal at 1 and 3 hours after infusion of another marketed recombinant Factor VIII concentrate. This single event results in a Factor VIII inhibitor frequency in PTPs of 0.51% (95% CI of 0.03 and 2.91% for the risk of any Factor VIII inhibitor development).[1,2] No Factor VIII inhibitors were detected in the 53 treated pediatric PTPs.

In clinical studies that enrolled previously untreated subjects (defined as having had up to 3 exposures to a Factor VIII product at the time of enrollment), 5 (20%) of 25 subjects who received ADVATE developed inhibitors to Factor VIII.[1] Four patients developed high titer (> 5 BU) and one patient developed low-titer inhibitors. Inhibitors were detected at a median of 11 exposure days (range 7 to 13 exposure days) to investigational product.

Immunogenicity also was evaluated by measuring the development of antibodies to heterologous proteins. 182 treated subjects were assessed for anti-Chinese hamster ovary (CHO) cell protein antibodies. Of these patients, 3 showed an upward trend in antibody titer over time and 4 showed repeated but transient elevations of antibodies. 182 treated subjects were assessed for mulgG protein antibodies. Of these, 10 showed an upward trend in anti-mulgG antibody titer over time and 2 showed repeated but transient elevations of antibodies. Four subjects who demonstrated antibody elevations reported isolated events of urticaria, pruritus, rash, and slightly elevated eosinophil counts. All of these subjects had numerous repeat exposures to the study product without recurrence of the events and a causal relationship between the antibody findings and these clinical events has not been established.

Of the 181 subjects who were treated and assessed for the presence of anti-human von Willebrand Factor (VWF) antibodies, none displayed laboratory evidence indicative of a positive serologic response.

Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of ADVATE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Among patients treated with ADVATE, cases of serious allergic/hypersensitivity reactions including anaphylaxis have been reported and Factor VIII inhibitor formation (observed predominantly in PUPs). Table 2 represents the most frequently reported post-marketing adverse reactions as MedDRA Preferred Terms.

Table 1
Summary of Adverse Reactions (ADRs)[a] with a Frequency ≥ 5% in 234 Treated Subjects[b]

MedDRA[c] System Organ Class	MedDRA Preferred Term	Number of ADRs	Number of Subjects	Percent of Subjects
General disorders and administration site conditions	Pyrexia	78	50	21
Nervous system disorders	Headache	104	49	21
Respiratory, thoracic and mediastinal disorders	Cough	75	44	19
Infections and infestations	Nasopharyngitis	61	40	17
Gastrointestinal disorders	Vomiting	35	27	12
Musculoskeletal and connective tissue disorders	Arthralgia	44	27	12
Injury, poisoning and procedural complications	Limb injury	55	24	10
Infections and infestations	Upper respiratory tract infection	24	20	9
Respiratory, thoracic and mediastinal disorders	Pharyngolaryngeal pain	23	20	9
Respiratory, thoracic and mediastinal disorders	Nasal congestion	24	19	8
Gastrointestinal disorders	Diarrhea	24	18	8
Gastrointestinal disorders	Nausea	21	17	8
General disorders and administration site conditions	Pain	19	17	8
Skin and subcutaneous tissue disorders	Rash	16	13	6
Infections and infestations	Ear infection	16	12	5
Injury, poisoning and procedural complications	Procedural pain	16	12	5
Respiratory, thoracic and mediastinal disorders	Rhinorrhea	15	12	5

[a] ADRs are defined as any Adverse Event that occurred within 24 hours after being infused with investigational product OR all Adverse Events assessed related or possibly related to investigational product OR Adverse Events for which the investigator's or sponsor's opinion of causality was missing or indeterminate.

[b] The ADVATE clinical program included 234 treated subjects from 5 completed studies in PTPs and 1 ongoing study in PUPs as of 27 March 2006.

[c] MedDRA version 8.1 was used.

Table 2
Post-Marketing Experience

Organ System [MedDRA Primary SOC]	Preferred Term
Immune system disorders	Anaphylactic reaction[a] Hypersensitivity[a]
Blood and lymphatic system disorders	Factor VIII inhibition
General disorders and administration site conditions	Injection site reaction Chills Fatigue/Malaise Chest discomfort/pain Less-than-expected therapeutic effect

[a] These reactions have been manifested by dizziness, paresthesias, rash, flushing, face swelling, urticaria, and/or pruritus.

References: 1. Shapiro A, Gruppo R, Pabinger I et al. Integrated analysis of safety and efficacy of a plasma- and albumin-free recombinant factor VIII (rAHF-PFM) from six clinical studies in patients with hemophilia A. Expert Opin Biol Ther 2009 9:273-283. **2.** Tarantino MD, Collins PW, Hay PW et al. Clinical evaluation of an advanced category antihaemophilic factor prepared using a plasma/albumin-free method: pharmacokinetics, efficacy, and safety in previously treated patients with haemophilia A. Haemophilia 2004 10:428-437.

To enroll in the confidential, industry-wide Patient Notification System, call 1-888-873-2838.

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RESEARCH FAQ'S

By Adam Kufen RN, BS, CCRC
Lead Research RN

The robust research department at the Hemophilia Center of Western PA brings a wide variety of studies to the patients of our treatment center. Patients have grown so accustomed to being presented with research opportunities, that if they aren't presented with them they seek them out themselves. Through all this exposure to various studies, we hear a number of commonly asked questions. This article highlights some of those Research FAQ's we hear at our center, some that you may have asked yourself.

Let's start this list with the big one, "What kind of study is this?" The type really sets the framework for the entire conversation we have with the patient. Our studies range from simple registries, which are the collection and assimilation of data from sources such as medical records, questionnaires, home treatment records, etc., to investigational drug trials, where subjects receive new medicine commonly referred to as "study drug" by our patients themselves. The first question is almost always followed with, "How much work will I (the patient) have to do?" I wish there was an easy general answer to this question but it truly is study dependent. At one end of the spectrum, we have data studies and you may only have to authorize release of your de-identified information. On the other end, an investigational drug study will most often require you to come in for frequent study visits, blood draws, extra physical exams, joint assessments, and so forth.

Knowing that participating in research requires commitments like the ones listed above, patients commonly ask, "Will I get paid for this?" First, subject payment requires clarification. We never pay subjects for participating. However, we understand that your time is valuable and knowing that study visits, diary entries, phone calls, travel, etc. can be time consuming, that is why it's possible we will compensate you. Any compensation provided directly relates to the intensity of the study; how many visits, assessments, and so on. With that said, most data type studies (questionnaires, registries) do not have compensation, while investigational drug trials may.

So, you were pitched a research study in our office and we talked to you about the type, the commitment, and any applicable compensation, but you wonder "If I sign up, what's different between being a research subject compared to a patient here?" On one hand, nothing, because our treatment center will still be committed to upholding your safety and placing your medical needs first. On the other hand, and I'm speaking to more labor intensive studies like "study factor" trials, there are quite a few things to note, but I will focus on the top three. First, you will transition part of your care to the research team, a group of research coordinators and nurses that work with Dr. Ragni specifically with subjects on studies, and I'm just one of those team members. Second, your research coordinator will manage all of your factor orders and deliveries. Third, we will ask you more questions than our clinic counterpart and actually more than would a news reporter! As a research subject, we want to know about every bleed, bump, and bruise; every cough and cold; and just about anything and everything you experience while on the study. Please don't be scared by this intensity, it's just our way to gather information.

This article only highlighted a few of the most commonly asked questions we hear in the research department. In closing, our center is committed to research in and for the bleeding disorder community. If at any time you have questions regarding our current studies or our research program, please phone the center and ask to speak with a research coordinator.

WINTERFEST

We were glad to recently welcome back Jeanette Cesta to speak at another Chapter event. Jeanette, a patient educator, presented the program entitled Another "RICE" for People with Bleeding Disorders, at the Winterfest program. Jeanette engaged the attendees by sharing her personal stories about living with a bleeding disorder. She talked about the importance of taking care of yourself, not just those you may care for, as well as the importance of getting involved in the bleeding disorders community, connecting with others who have a bleeding disorder, and becoming educated on your bleeding disorder.

The Winterfest program was held on December 1, at the Heinz History Center. Following the program, the attendees had an additional opportunity to talk with Jeanette, network with each other, and enjoy the rest of the day at the History Center.

INDUSTRY NEWS

Family Inhibitor Camp Date Change
CHES (Comprehensive Health Education Services, LLC) is hosting two Family Inhibitor Camps in 2013. The first session will be held in California, at the Painted Turtle Camp, on April 19-22, 2013. The second session will be held in North Carolina, at Victory Junction, on October 17-20, 2013. (Note: These are new dates for the session at Victory Junction).
The Family Inhibitor Camps offer a full weekend of education, support, and fun designed specifically for children with hemophilia and active inhibitors. For more information, visit http://www.comphealthed.com and select Family Inhibitor Camp.

Victory for Women
Are you a woman with a diagnosed bleeding disorder or suspect you might have one? If so, you should know about Victory for Women (V4W)! This is the National Hemophilia Foundation's health initiative to address the critical issues faced by women with bleeding disorders. V4W has two main goals. The first is to increase awareness of women's bleeding disorders so that girls and women receive early, accurate diagnoses, leading to better health outcomes. The second is to provide women affected by bleeding disorders with the education, support, skills and resources they need to advocate for their healthcare, financial and social support needs.
The National Hemophilia Foundation has a website dedicated to this initiative. The Victory for Women Website contains specific information for Diagnosed Women, Undiagnosed Women, and Healthcare Providers. To learn more, visit the website at: http://www.victoryforwomen.org.

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* You must be currently covered by a private (commercial) insurance plan. If you are not eligible for the XYNTHA Trial Prescription Program, you may find help accessing Pfizer medicines by contacting Pfizer's RSVP program at 1-888-327-RSVP (7787).

What Is XYNTHA?

Xyntha® Antihemophilic Factor (Recombinant), Plasma/Albumin-Free is indicated for the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for surgical prophylaxis in patients with hemophilia A.

XYNTHA does not contain von Willebrand factor and, therefore, is not indicated in von Willebrand's disease.

Important Safety Information for XYNTHA

- Call your healthcare provider or go to the emergency department right away if you have any of the following symptoms because these may be signs of a serious allergic reaction: wheezing, trouble breathing, chest tightness, turning blue (look at lips and gums), fast heartbeat, swelling of the face, faintness, rash, or hives. XYNTHA contains trace amounts of hamster protein. You may develop an allergic reaction to these proteins. Tell your healthcare provider if you have had an allergic reaction to hamster protein.
- Call your healthcare provider right away if bleeding is not controlled after using XYNTHA; this may be a sign of an inhibitor, an antibody that may stop XYNTHA from working properly. Your healthcare provider may need to take blood tests to monitor for inhibitors.
- The most common adverse reaction in the safety and efficacy study is headache (24% of subjects) and in the surgery study is fever (43% of subjects). Other common side effects of XYNTHA include nausea, vomiting, diarrhea, or weakness.
- XYNTHA is an injectable medicine administered by intravenous (IV) infusion. You may experience local irritation when infusing XYNTHA after reconstitution in XYNTHA® SOLOFUSE®.

Please see brief summary of full Prescribing Information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Pfizer

xyntha®

Antihemophilic Factor (Recombinant), Plasma/Albumin-Free

xyntha® solofuse®

Antihemophilic Factor (Recombinant), Plasma/Albumin-Free

℞ only

Brief Summary

See package insert for full Prescribing Information, including patient labeling. For further product information and current patient labeling, please visit XYNTHA.com or call Wyeth Pharmaceuticals toll-free at 1-800-934-5556.

Please read this Patient Information carefully before using XYNTHA and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical problems or your treatment.

What is XYNTHA?

XYNTHA is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia A. Hemophilia A is also called classic hemophilia.

XYNTHA is not used to treat von Willebrand's disease.

What should I tell my healthcare provider before using XYNTHA?

Tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or planning to become pregnant. It is not known if XYNTHA may harm your unborn baby.
- are breastfeeding. It is not known if XYNTHA passes into your milk and if it can harm your baby.

Tell your healthcare provider and pharmacist about all of the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies.

XYNTHA contains trace amounts of hamster proteins. You should not use XYNTHA if you are allergic to hamster protein.

How should I infuse XYNTHA?

Step-by-step instructions for infusing with XYNTHA are provided at the end of the complete Patient Information leaflet. The steps listed below are general guidelines for using XYNTHA. Always follow any specific instructions from your healthcare provider. If you are unsure of the procedures, please call your healthcare provider before using.

Call your healthcare provider right away if bleeding is not controlled after using XYNTHA. Your body can also make antibodies against XYNTHA (called "inhibitors") that may stop XYNTHA from working properly. Your healthcare provider may need to take blood tests from time to time to monitor for inhibitors.

Call your healthcare provider right away if you take more than the dose you should take.

Talk to your healthcare provider before traveling. Plan to bring enough XYNTHA for your treatment during this time.

What are the possible or reasonably likely side effects of XYNTHA?

Common side effects of XYNTHA are

- headache
- fever
- nausea
- vomiting
- diarrhea
- weakness

Call your healthcare provider or go to the emergency department right away if you have any of the following symptoms because these may be signs of a serious allergic reaction:

- **wheezing**
- **difficulty breathing**
- **chest tightness**
- **turning blue (look at lips and gums)**
- **fast heartbeat**
- **swelling of the face**
- **faintness**
- **rash**
- **hives**

Talk to your healthcare provider about any side effect that bothers you or that does not go away. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XYNTHA?

Do not freeze.

Protect from light.

XYNTHA Vials

Store XYNTHA in the refrigerator at 36° to 46°F (2° to 8°C). Store the diluent syringe at 36° to 77°F (2° to 25°C).

XYNTHA can last at room temperature (below 77°F) for up to 3 months. If you store XYNTHA at room temperature, carefully write down the date you put XYNTHA at room temperature, so you will know when to either put it back in the refrigerator, use it immediately, or throw it away. There is a space on the carton for you to write the date.

If stored at room temperature, XYNTHA can be returned one time to the refrigerator until the expiration date. Do not store at room temperature and return it to the refrigerator more than once. Throw away any unused XYNTHA after the expiration date.

Infuse XYNTHA within 3 hours of reconstitution. You can keep the reconstituted solution at room temperature before infusion, but if you have not used it in 3 hours, throw it away.

Do not use reconstituted XYNTHA if it is not clear to slightly opalescent and colorless.

Dispose of all materials, whether reconstituted or not, in an appropriate medical waste container.

XYNTHA SOLOFUSE

Store in the refrigerator at 36° to 46°F (2° to 8°C).

XYNTHA SOLOFUSE can last at room temperature (below 77°F) for up to 3 months. If you store XYNTHA SOLOFUSE at room temperature, carefully write down the date you put XYNTHA SOLOFUSE at room temperature, so you will know when to throw it away. There is a space on the carton for you to write the date.

Throw away any unused XYNTHA SOLOFUSE after the expiration date.

Infuse within 3 hours after reconstitution or after removal of the grey rubber tip cap from the prefilled dual-chamber syringe. You can keep the reconstituted solution at room temperature before infusion, but if it is not used in 3 hours, throw it away.

Do not use reconstituted XYNTHA if it is not clear to slightly opalescent and colorless.

Dispose of all materials, whether reconstituted or not, in an appropriate medical waste container.

What else should I know about XYNTHA?

Medicines are sometimes prescribed for purposes other than those listed here. Talk to your healthcare provider if you have any concerns. You can ask your healthcare provider for information about XYNTHA that was written for healthcare professionals.

Do not share XYNTHA with other people, even if they have the same symptoms that you have.

This brief summary is based on the Xyntha® [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free] Prescribing Information LAB-0516-3.0, revised 06/12, and LAB-0500-7.0, revised 06/12.

Wyeth®

Manufactured by Wyeth Pharmaceuticals Inc.

Marketed by Pfizer Inc.

Pfizer

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INFUSION DAY – MARCH 2, 2013

Infusion Day

Are you considering home infusion and want to see what it's all about? Have you been trained in home infusion and want a refresher? Would you like to have a babysitter, grandparent, spouse, sibling, other relative or caregiver learn how to infuse you or your child? Then Infusion Day is for you!

You and your family/caregivers will have the opportunity to learn about home infusion with instruction from nurses from the Hemophilia Center of Western PA. This program is full of hands-on activities. In a fun and safe environment, you will learn how to find good veins and you will practice infusing with a training kit and fake vein. And for the brave…you can practice accessing a real vein, under the careful guidance of a nurse!

RSVP

Please RSVP by Friday, February 22, 2013 at 724-741-6160 or send an e-mail to rsvp@westpennhemophilia.org. Please be sure to include your first and last name, phone number, e-mail address, total number in party, and number of children. Also, please include the ages of children 12 and under.

There's no cost to attend this event.

Date, Time, & Location

Presenter:	Kristen Jaworski RN, BSN, CCRC Hemophilia Center of Western Pennsylvania
Date:	Saturday, March 2, 2013
Time:	10:00 a.m. Registration 10:15 a.m. Brief Home Infusion Overview 10:30 a.m. Learning Stations Staffed by HCWP Nurses
Location:	Regional Learning Alliance Great Room 850 Cranberry Woods Drive Cranberry Township, PA 16066
Directions:	For directions, visit the Regional Learning Alliance website: http://www.therla.org/visit

The Hemophilia Center of Western Pennsylvania

The Hemophilia Center of Western Pennsylvania clotting factor program was established in 2000 as a complement to the Center's other comprehensive care services. The clotting factor program allows the Center the opportunity to offer clotting factor to its patients, thereby supplementing its comprehensive treatment care model and providing the best possible care for its patients.

Please contact the Center at (412) 209-7280 for more information about how this program can benefit you and the entire bleeding disorder community.

The Hemophilia Center of Western Pennsylvania supports patient choice consistent with the Veterans Health Care Act of 1992 and maintains a freedom of choice policy where patients are informed of their choices regarding factor replacement products.

Factor Program Services

- All factor product brands available
- Online factor ordering available
- 24 – 48 hour delivery
- Same day courier service for emergent needs
- On-call services, 24/7
- Home treatment supplies
- Lot tracking for recall notification
- Online home treatment records
- Insurance benefit information assistance

Patient Benefits

- Direct communication and service from the Center's treatment team
- Support of the Center's operations
- Expansion of patient services

ORGAN TRANSPLANTS INCREASING IN HIV PATIENTS

An October Wall Street Journal (WSJ) article highlights a new trend--an increase in the number of organ transplants in HIV-positive patients. Historically, centers have been reluctant to conduct vital organ transplants in these patients for a number of reasons. There have been concerns that recipients would not live long, that HIV-associated diseases would damage the transplanted organ and that anti-rejection drugs might degrade organ functions. However, highly effective anti-retroviral therapies (ART), available since the mid-1990s, have enhanced overall health and life expectancy (32.1 years after diagnosis) for HIV patients to such a degree that organ transplantation is now becoming a viable clinical option. In fact, aging HIV-positive patients are now encountering many of the same health issues as the general population, often necessitating liver, kidney and heart transplants.

"There are so many patients who are [HIV-positive] but are in good shape and look better than other patients that we transplant," said Hiroo Takayama, MD, PhD, a surgeon at New York-Presbyterian Hospital/ Columbia University Medical Center. Takayama has done two heart transplants in HIV-positive patients. "So the question is whether we really should eliminate those patients—should we let them die just because they are HIV-positive?" The center is currently conducting long-term post-transplant follow-ups on 11 HIV-positive people who have had heart transplants, a situation that, as the WSJ piece notes, would have been unprecedented just five years ago.

According to the United Network for Organ Sharing, the nonprofit organization that manages the US transplant system, the number of centers that reported doing transplants on HIV-positive patients increased in 2011 to at least 48 centers out of the 242 that perform transplants. In contrast, only 25 centers reported conducting such procedures in 2005. The overall number of transplants may be even higher because some states prohibit reporting information relevant to HIV status. In addition, at least 198 HIV-positive patients received organ transplants in 2011, up from approximately 58 performed in 2005.

Evidence of the new trend can be found in such institutions as the Hartford Hospital (HH) in Connecticut. HH actually rewrote protocols earlier in 2012 to make possible the centers first heart transplant in an HIV-positive patient, a procedure barred under previous protocols. As part of the new protocol, a candidate needs to have taken anti-retroviral drugs for a minimum of one year and demonstrate undetectable viral loads. "There is a scarcity of donor hearts, and we want to make sure every patient will survive," said Detlef Wencker, director of heart-failure services and cardiac transplantation at HH.

The WSJ article also acknowledged that hurdles still exist for HIV patients needing transplants. Physicians must carefully manage the complex interactions between ART and organ rejection drugs, plus the possible long-term effect on the health of the transplanted organ. Another red flag for doctors is the lack of available outcome data on transplants in HIV-positive patients. Existing data suggest that providers should be aware of potential complications. In a recently completed study, researchers at Massachusetts General Hospital found that patients with undetectable HIV levels had inflammation in their aortas comparable to people with known cardiovascular disease. Other studies suggest that HIV-infected patients are at twice the risk for heart attacks and strokes as HIV-negative individuals.

While providers continue to weigh the risks vs. rewards associated with organ transplants, a consensus seems to be that more long-term outcome data can only be beneficial. Transplant surgeon Peter Stock, MD, PhD, is professor of surgery at the University of California, San Francisco School of Medicine. He is principal investigator of a multicenter trial of kidney and liver transplants in HIV-positive patients. Findings from the trial, which was sponsored by the National Institutes of Health, showed that HIV-positive transplant patients responded well overall. Although Stock reported a two-to-three fold higher incidence of kidney rejection, he added that this incidence could be lowered by using immunosuppressant drugs.

Stock also stressed that the long-term health of the transplanted organ remains unknown but other health conditions "takes life out of the kidney." While the effects might not show up in the short-term when measured against the general population, "we might start to see differences in survival in five or 10 years," concluded Stark.

Source: The Wall Street Journal, October 11, 2012

SPOTLIGHT ON THE MEMBER

When Joseph Desalvo was born his parents had no idea that he had hemophilia. There had been no family history, and it would be a number of years before he would receive an official diagnosis of severe Hemophilia B.

When he was 2 years old, Joe ran into the street and was hit by a car. He would spend the next month in coma, receiving blood for unexplained bleeding. Joe beat the odds and recovered from the accident.

Joe was not a stranger to the hospital during his childhood. By the time he was 11, he received his official diagnosis and was receiving Factor IX to help control bleeds. When he was in the 6th grade, he was hospitalized for 3 weeks and suffered nerve damage in one of his legs. He recalls the challenges and feelings of isolation during his childhood, especially when he was dealing with a bleed and could only watch other kids play. When he was 12, he traveled to Italy with is family for a vacation, and regrettably, he developed a bleed. Although his parents brought factor with them, they couldn't find a doctor willing to infuse him. Unfortunately, he had to wait out the bleed in a hotel room.

Things began to turn around for Joe when he was 15 years old and started infusing at home. That year he was well enough to attend camp for the first time. He attended Camp Variety and spent a week with other boys who had hemophilia. He said that week at camp was a great experience and when he was older, he came back to volunteer at the camp.

Even though much has improved over the years, Joe needed to have both of knees replaced about three years ago, due to permanent damage. However, Joe says that due to continued advancements in Factor, today, at age 51, he is living a better life than he did in his younger years. He also credits Dr. Margaret Ragni for helping him get to where he is today. He states that she's a gifted and compassionate doctor.

Joe is happily married to Kathy, and is the proud father of their 7 children: Jazmin, 20; David, 19; Paolo, 16; Christian, 11; Jonathan, 11; Elia,7; and Elijha, 7! They reside in Allison Park, PA. He enjoys spending time with his family and taking them to Pittsburgh attractions, like the Carnegie Science

Center. They also enjoy movie nights at home. He is also very involved in his church and mission work.

As a long-time member of the Chapter, Joe has attended many events over the years. His favorite are the Men's Group events--particularly, the Pittsburgh Pirate baseball games. If you attended the Chapter's Annual Meeting and Walk Kickoff at PNC Park this past July, you would have seen Joe be presented with the Don Groves Memorial Scholarship award.

Joe is currently working and attending Ministry School. His ministry work includes helping people to overcome addictions and find jobs. He works in and around the Pittsburgh area reaching out to the homeless and helping them see beyond their current situation, realize their gifts, and become contributors to society. His goal is helping them turn their lives around and become leaders. He says he has a call and a passion to help those who struggle because he has struggled. He views his condition as a blessing. He believes that when we realize what we have overcome, it makes us stronger and we can become leaders and teach others to overcome their trials. He advises others to turn a disability into an ability to help others. He believes a disability is not your identity; it's your strength!

TAKE-A-BOUGH

Continued from page 1

extravaganza by setting up 102 trees, wreaths and tabletop displays donated by individuals and businesses from all over Western Pennsylvania.

From November 16-18 the event was open to the public. Hundreds of people passed through the decorated holiday items throughout the three day event. We had Santa join us for Saturday and Sunday and people were able to purchase pictures of their children with him. A raffle for a $550 "Done in a Day" gift card tree was offered for $5/ticket and was won by Teresa D'Appolonia.

The event ended with a beautiful Donor Reception on November 19 where Dr. Margaret Ragni of the Hemophilia Center of Western Pennsylvania inspired us with her encouraging words. Dawn Rotellini and Alison Yazer also spoke and both wished Madonna McGuire Smith the best as she and her family relocate to Oregon to start a new chapter in their lives!

A very big thank you goes out to all who sponsored the event, donated items and volunteered their time to help make the event such a resounding success!

Mark your calendars for November 22-24, 2013! Look for more information to come!

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Staff office hours are Monday through Friday from 9 a.m. until 4 p.m. Every attempt will be made to return calls received during regular office hours on the same day.

Our Mission:

The Western Pennsylvania Chapter of the National Hemophilia Foundation is leading the way in Western Pennsylvania in improving the quality of care and enriching the lives of those with bleeding disorders through education, advocacy, resource, and referral.

WPCNHF Wish List

The Chapter is always doing fundraisers to raise money for our educational programs and member support activities but sometimes we just need a few small things for the office. WPCNHF has a list of items needed in the office. If you, or anyone you know, is interested in donating any of the following please contact the office at info@westpennhemophilia.org or call us at 724-741-6160.

- White copy paper by the ream or by the case
- Colored copy paper by the ream for invitations and newsletter inserts
- Legal pads for note taking
- Forever U.S. Postage stamps
- 10 x 13 Ready-seal envelopes for newsletter mailings
- Paper towels
- Apartment-sized refrigerator
- Small microwave oven
- Conference table and chairs
- Waiting room chairs

HAPPY NEW YEAR

Thank you for allowing us to serve
You during 2012
Wishing you a happy and healthy
New Year for 2013!

From the staff at the Hemophilia Center
of Western Pennsylvania

Please visit our enhanced website coming soon at hcwp.net

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Cranberry Township, PA 16066
Phone: 724-741-6160 Toll Free: 800-824-0016 Fax: 724-741-6167
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WPCNHF